

### **III. REMARKS/ARGUMENTS**

#### **A. Status of the Application**

Claims 1, 8-17, 19 and 39 are under examination in this application. Claims 28-38 are withdrawn from examination. Favorable consideration of claims 1, 8-17, 19 and 39 in light of the following remarks is respectfully requested.

#### **B. Rejection of Claims 1, 8-17 and 19 under 35 U.S.C. § 103(a) over Donzis, Paul, Plaut and McAnalley.**

Claims 1, 8-17 and 19 stand rejected under 35 U.S.C. § 103(a) over the combination of U.S. Patent No. 5,576,015 to Donzis ("Donzis"), U.S. Patent No. 5,531,989 to Paul ("Paul"), International Patent Application Publication Nos. WO 97/05884 to Plaut ("Plaut") and WO 98/06418 to McAnalley ("McAnalley"). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Claim 1 is directed to a dietary supplement composition for a mammal, comprising a nutritionally effective amount of  $\beta$ -glucan, colostrum, lactoferrin, citrus pectin and a nutritionally effective amount of six or more essential saccharides. Claims 8-17 and 19 depend, directly or indirectly, and include the subject matter of claim 1.

Applicant submits that the combination of Donzis, Paul, Plaut and McAnalley fails to teach each and every limitation of the amended claims, specifically a composition that includes six or more essential saccharides in a nutritionally effective amount. Therefore, it is requested that the rejection of claims 1, 8-17 and 19 under 35 U.S.C. § 103(a) over the combination of Donzis, Paul, Plaut and McAnalley, be withdrawn.

Applicant submits that Paul does not teach or reasonably suggest the composition of the present invention. In fact, Paul teaches against the use of colostrum by specifically using isolated and purified immunoglobulins rather than colostrum. If Paul had wanted to include colostrum in the composition, they could simply have done so. Because Paul does not include the limitation listed, it fails to provide support for a finding of obviousness.

Plaut is used in the Office Action to add the component that Paul is missing, i.e., colostrum. In the Office Action, it is argued by the Examiner that colostrum and isolated and

purified immunoglobulins may be used interchangeably in a composition. However, Paul makes no such teaching because of the purpose of its invention, that is, to use highly purified immunoglobulins separate and apart from the other components in colostrum. If Paul had intended to use colostrum as a substitute they would have done so.

Not having found the required components in the art, the Office Action then reaches to a third reference, namely, Donzis, to argue that the skilled artisan would have selected this reference out of thousands of references to dietary supplements to achieve the present invention. However, neither Paul, nor Plaut require the addition of a beta-glucan for their invention. Again, if either reference had intended to include such a component, they could simply have done so. As regards the statement that these three reference include "saccharides" the Applicant strongly traverses this argument as the contribution of the beta-glucan is not taught anywhere to be directed to the addition of a nutritionally effective amount of six or more essential saccharides. Even a minimally skilled artisan will recognize that beta-glucans are polysaccharides of D-glucose connected at the 1 and 3 positions. Therefore, Donzis only contributes the use of a single saccharide, namely D-glucose, and does not disclose or suggest the addition of a nutritionally effective amount of six or more essential saccharides.

Reaching to a fourth reference to cobble together the present invention, the Office Action next cites McAnalley. McAnalley is combined with the other three references to teach that a composition can include six or more essential saccharides. The addition of McAnalley fails for two reasons. First, the combination fails because Donzis fails to provide the link between colostrum/lactoferrin/beta glucans and citrus pectin and six or more saccharides. The combination also fails because nothing in McAnalley would lead a skilled artisan to combine it in the reverse direction, that is, with the other references.

Accordingly, a prima facie case of obviousness has not been established because each and every limitation of claims 1, 8-17 and 19 is not taught by the combination of Paul, Donzis, Plaut and McAnalley. Specifically, the combination of cited references does not teach a composition that includes six or more essential saccharides and even if it did the combination does not teach a composition that includes colostrum, lactoferrin,  $\beta$ -glucan, citrus pectin, and a nutritionally effective amount of six or more of such essential saccharides. For these reasons, Applicant respectfully requests withdrawal of the rejection and allowance of the claims.

**B. Rejection of Claims 1, 8-17, 19 and 39 under 35 U.S.C. § 103(a)**

Claims 1, 8-17, 19 and 39 stand rejected under 35 U.S.C. § 103(a) over the combination of U.S. Patent No. 6,258,383 to Gohlke (“Gohlke”), U.S. Patent No. 5,576,015 to Donzis (“Donzis”), and International Patent Application Publication WO 98/06418 to McAnalley (“McAnalley”). Insofar as it may be applied against the present claims, this rejection is respectfully traversed and the arguments as regards Donzis and McAnalley are incorporated herein by reference.

As noted above, claim 1 is directed to a dietary supplement composition for a mammal, comprising a nutritionally effective amount of  $\beta$ -glucan, colostrum, lactoferrin, citrus pectin and a nutritionally effective amount of six or more essential saccharides. Claims 8-17 and 19 depend, directly or indirectly, and include the subject matter of claim 1.

Claim 39 is directed to a dietary supplement composition for a mammal consisting essentially of from 5 to 83.3 weight percent of colostrum, from 0.909 to 6.67 weight percent of lactoferrin, from 0.1 to 1.25 weight percent of citrus pectin, from 0.001 to 10 weight percent of  $\beta$ -glucan and a nutritionally effective amount of six or more essential saccharides adapted for adsorption in the digestive tract.

The newly cited reference to Gohlke, teaches a composition that includes colostrum, lactoferrin and optionally citrus pectin. However, Gohlke specifically teaches that the composition is adapted for oral uptake and that the compositions are in the form of lozenges. The skilled artisan in light of Gohlke will recognize that when a composition is administered for a “mucosal delivery format” as taught by the reference, it has been adapted for “adsorption” in the “oral cavity” (See column 6, ll. 22-26). In fact, the “Object of the Invention” teaches away from the present invention by specifically stating that the composition is not intended for digestive delivery, but rather, it is intended to “avoid the body’s normal digestive mechanisms.” (Col. 5, ll. 63-66). The “object of the invention” states, in fact, that the “supplement must be provided in a convenient format that permits absorption of the active components,” in the mouth and not the digestive tract.

In contrast, the present invention is for delivery of effective amounts of the composition to the digestive tract. Furthermore, the skilled artisan will also recognize the art recognized meaning of the term “lozenge”, which is a small, medicated candy. Candy is a specific

formulation of crystallized sugars that are formulated in products such as Sucrets®, Vicks® and Ricola®-type products. The fact that the art is limited to lozenges is clear from the cited “object” of the invention, which is to provide for oral adsorption of the composition. Therefore, for at least two separate reasons Gohlke teaches away from the present invention.

Accordingly, a prima facie case of obviousness has not been established because each and every limitation of claims 1, 8-17, 19 and 39 is not taught by the combination of Gohlke, Donzis and McAnalley. Specifically, the combination of cited references does not teach a composition that includes six or more essential saccharides and even if it did the combination does not teach a composition that includes colostrum, lactoferrin,  $\beta$ -glucan, citrus pectin and a nutritionally effective amount of six or more of such essential saccharides. Applicant respectfully requests withdrawal of the rejection and allowance of the claims.

**D. CONCLUSION**

In light of the foregoing, Applicant submits that claims 1, 8-17, 19 and 39 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited. The Examiner is invited to call the undersigned at the below-listed telephone number if a telephone conference would expedite or aid the prosecution and examination of this application.

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Respectfully submitted,



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